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Navigation system for performing and assisting surgical operations, marking device or fiducial, and pointer for a tracking device in a navigation system

DESCRIPTION

The invention relates to a navigation system for performing and assisting surgical operations, in particular in the area of neurosurgery and ear-nose-throat medicine, to a marking device or fiducial for producing image data for a database by means of nuclear-spin and/or computer tomography and for detecting the position of a test subject and assigning coordinates for surgical operations assisted by a navigation system, and to a pointer for a tracking device in a navigation system.

Neuro-navigation systems provide assistance during surgical operations on the skull. Known navigation systems enable the position of a surgical instrument within the operation field to be indicated, so that small, deep-seated lesions in the brain can be reliably targeted in an atraumatic manner. During operations in the area of ENT medicine, for example, a navigation system can be used to distinguish reliably between the boundaries of the paranasal sinuses and the brain.

Navigation systems that operate with various tracking methods are known. For example, reference is made here to the StealthStation system made by Sofamor Danek Inc, USA. With the known systems the first step is to obtain a preoperative image of the anatomy or the brain of the subject or patient. Then a tracking system with optical sensor can be used to display

slices or views of the brain on a monitor, on the basis of the image data obtained preoperatively. During the preoperative scanning by means of computer and/or nuclear-spin tomography so-called fiducial markers are attached to the surface of the patient's head. These fiducials serve to identify the location of the images, taking into account the spatial orientation in each case.

The use of known systems is restricted by an elaborate structure of the equipment and by the fact that they are complicated and time-consuming to operate, especially during optical tracking.

Tracking methods are also known that rely on alternating magnetic fields to detect the position of a pointer for the imaging system; these are not well suited for use in surroundings that produce magnetic interference, as is routinely the case in the clinical context.

Further disadvantages of known systems are associated with the complexity involved in requiring the operator to manipulate a computer keyboard as well as the pointer, in order to record the image or to carry out controlling or marking procedures.

In the case in which optical sensors or optical tracking are employed, elaborate calibrations must be performed, in particular when the operating table bearing the patient is moved in space, so that undesired changes in position of the optical sensor system are produced. To overcome such problems an optical reference system is attached to the skull, or to the head-holder that is fixed to the skull. Although this does overcome the calibration problem, the reference markers are so large and susceptible to mechanical alteration that they have a disturbing effect during the operation.

Previously known fiducials, i.e. marking devices for producing image data by means of nuclear-spin and/or computer tomography

or determining the position of a subject and assigning coordinates for surgical operations assisted by a navigation system, are of relatively large spatial dimensions and hamper the patient unpleasantly, especially because considerable time elapses between the procedure of taking pictures by nuclear-spin or computer tomography and the subsequent surgical procedure. That is, for assigning coordinates the fiducial must remain on the patient's head, which is obviously unpleasant.

The pointers needed for a tracking device of a navigation system, for which the terms "stylus" or "pen" are also used, must meet clinical requirements including the requirement for sterilizability, in particular sterilization by steam. At the same time such pointers should be easily and simply manipulated and comprise appropriate means for triggering switching or control commands.

An objective of the invention, derived from the above, is to disclose a complex navigation system for performing and assisting surgical operations in which a tracking-sensor device is employed that enables extremely precise detection of position without restricting the operation field or hindering the activity of the operator. Furthermore, the navigation system should enable nearly real-time 3D visualization in the desired direction of view, which is specified by means of a pointer, on the basis of preoperative images or an image database. With the navigation system to be created it should also be possible to control the necessary processes for visualization, storage and so on with only one hand.

A further objective of the invention is to create a marking device or fiducial to produce image data for a database by means of nuclear-spin and/or computer tomography that serves simultaneously to detect the position of a subject and assign coordinates for surgical operations without the patient suffering any disadvantages from the fact that the

preoperatively attached marking device must remain in place until the operation has been performed.

Finally, the invention is intended to provide a pointer or stylus for a tracking device of a navigation system for carrying out and assisting surgical operations on the basis of an elongated handpiece housing, such that the pointer should satisfy all of the clinical requirements and be resistant to the mechanical-thermal stresses of sterilization.

These objectives are achieved with respect to the navigation system by the definition according to the teaching of Claim 1; with respect to the marking device or fiducial with an object according to the characteristics given in Claim 8; and regarding the pointer for a tracking device of a navigation system by a combination of characteristics such as is disclosed in Claim 13.

The subordinate claims represent at least advantageous embodiments and further developments of the respective subject matter or of the system.

The basic idea of the invention regarding the navigation system for carrying out and assisting surgical operations consists in the further development of known solutions in such a way that to implement the tracking device for detecting the momentary position of an instrument and deriving or redrawing in real time representations of the patient's anatomy on the basis of images stored in an image databank, means are employed to generate a specified constant magnetic field in the navigation environment, so that a pointer navigation instrument is used that comprises an integral magnetic-field sensor tuned to the constant magnetic field of the transmitter.

The invention further provides a software module by means of which anatomical structures are extracted from the sets of raw

data derived from the preoperative images and these structures are made available in the form of visualizable 3D data sets.

By the above-mentioned image-processing module anatomical structures can be selected according to their properties or surroundings from the complete input data sets obtained preoperatively, and can be converted into discrete data sets on the basis of a predeterminable segmentation strategy.

Another basic idea of the navigation system in accordance with the invention is to employ means that permit menu-guided control of the system by movement of the pointer navigation instrument outside the operation field but within a navigation environment, such that activation or deactivation of displayed menus or control functions can be accomplished entirely by the previously mentioned movement of the navigation instrument.

The special constant-field transmitter to generate a magnetic field for the tracking device is disposed at the operating table or a head-support provided there, so that it is stably positioned with respect to the subject but is outside the operation field and hence causes no interference. As a result, the transmitter is in a spatially fixed, reproducible relation to the subject, who is fixed to or on the operating table, in particular to or on a head-support, regardless of the spatial position of the operating table itself.

The magnetic-field sensor makes available signals for recording position and/or direction of movement of the pointer navigation instrument on the basis of the specified constant magnetic field and its orientation, such that these signals can be displayed on a monitor and also used to control reloading and updating by the image-processing module.

In a preferred embodiment of the invention an additional magnetic-field sensor is provided, which can be attached to the subject, preferably cranially (i.e. to the skull) or to another

part of the body to be navigated. As a result, changes in location and orientation of the skull or other part of the body with respect to the constant-field transmitter can be detected. By means of this additional sensor, positional alterations that otherwise would necessitate new initializing measurements or adjustments of the system are correlated or compensated automatically within the system. In this case, if the surgical technique requires it, the operator can change the position of the skull as desired, with no limitation imposed on the navigation owing to a lack of adjustment or the need for readjustment. In other words, the additional magnetic-field sensor makes available corrective data that are sent to the control computer to to determine a quasi-dynamic or alterable (with reference to the source alteration) coordinate system.

Using the system briefly described above, the surgeon or system operator has considerably less work to do and the number of possible sources of error during the operation is reduced. This is made possible in particular by the virtual control panel, by means of which the surgeon can make use of and control all the essential functions of the navigation system and the computer implemented there, with no help from anyone else. In detail, it is possible to change the forms of representation and the views of the anatomical structures and/or to turn on specific functions. For this purpose an easily surveyed menu on the monitor or display is used, such that activation or deactivation is achieved by the above-mentioned simple spatial movement of the navigation instrument outside the operation field.

The use of a tracking system based on measurement of the field strength of constant magnetic fields effectively suppresses signal distortions caused by electromagnetically induced field superposition. The components of the navigation system, in particular the constant-field transmitter, can be disposed beneath sterile operation-field coverings, so that the surgeon's field of view and its immediate surroundings are not

restricted, and there is no interference with the surgical procedure. In comparison to optical navigation systems, the solution in accordance with the invention is structurally insensitive to mechanical impacts. Furthermore, the patient can be freely moved in space along with the operating table, without navigational restriction. The automated image processing in the present system substantially shortens the preparation times, and the 3D representation of the brain on the monitor and the view of the brain obtained after craniotomy are identical, so that the surgeon has more opportunity to plan the operation before it is begun.

In order to use the navigation system, the head of the patient is fixed in position by the neurosurgeon prior to the operation in the manner known per se, employing the appropriate mechanical head supports. The head-support system can be made of conventional materials such as aluminium or high-alloy steel, with no risk of interference with the tracking device. By means of the navigation system the patient's head position is recorded during the initializing measurements, and at first an image perspective from the viewpoint of the surgeon is presented automatically as a 3D graphic. The position of the operating table itself has no influence on the navigation process, because the head-holder and the transmitter of the tracking device are in a fixed orientation with respect to one another.

For preferred neurosurgical application, as described, first the 3D picture of the brain is presented as it appears to the surgeon at the beginning of the operation. However, this perspective can be altered at any time by means of the navigation instrument, i.e. the pointer, which will be described later.

In one embodiment of the invention the navigation system has the supplementary function of enabling electrophysiological measurements to be documented. For this purpose, the monitor

display of the brain surface can be marked by means of the navigation instrument, i.e. the pointer. With the pointer/stylus the desired marks, so-called tags, can be made on paper and these positions stored by pressing a key. The operators can select numerals and colours by way of a control field displayed on the monitor. In addition it is possible to supplement the documentation with a time label. The documents so produced can be stored and printed out at a later time by a connected printer, which is advantageous for subsequent description and evaluation of the operation.

For navigation, as is generally known, it is necessary to create a registration between the virtual image of the brain and the real brain of the patient lying on the operating table in theatre. For this purpose unambiguous reference points are needed, which can be found again in both the real and the virtual system. Fundamentally anatomical landmarks are used, althugh owing to displacements of the skin and to the size of the landmarks it is not always possible to achieve great precision.

For this reason known navigation systems comprise additional reference points, specifically termed markers or fiducials. These markers are made of materials that are detectable in nuclear-spin and/or computer tomography.

Some known marker systems that conform to the precision required, and take into account the possibility of skin displacement, are fixed in position by screwing them to the skull bone. Alternatives consist in using mouthpieces on which the patient must bite during the tomographic examination as well as in the operating theatre. Such methods are associated with a large financial and temporal expenditure and are extremely unpleasant for the patient. Markers generally can be screwed in only by a physician because of the invasive nature of this treatment, which further increases the costs.

Hence according to a supplementary basic idea of the invention, a special marking device or fiducial was created for producing image data for a database by tomography on one hand, and on the other hand also for monitoring the position of a subject and assigning coordinates for the surgical operation.

In accordance with the invention a carrier is present in the form of a flat, at least partially flexible structure with a catch knob substantially centred on the side away from the adhesive surface.

The actual marking substance is contained in a substantially cylindrical housing that can easily be handled. The underside of the housing preferably has a concave form or is recessed, and on this underside is disposed a substantially centred catch receptacle or a counterpart to the catch knob.

The catch knob on one hand and the receptacle or counterpart on the other hand make it possible to attach the cylindrical housing after the carrier has been fixed to the subject, or to release the housing at a later time and reattach it. Thus the patient can have the relatively large-volume cylindrical housing containing the marking substance removed after, or in an interval during, the tomography and move about unimpeded. Then for continuing the tomography and for the subsequent operation, the cylindrical housings can be attached again in exactly the same position, or special accessories for the initializaing measurement can be attached in the operating theatre by making use of the catch knob.

The selected adhesive coating in combination with the concave or recessed shape of the housing floor, the curvature of which corresponds approximately to that of the skull, ensures that the filmlike carrier or the adhesive plate is pulled close to the plastic element, i.e. the housing for the marking substance. This feature makes it possible for the distance between marking substance, which is contained for instance in a

spherical housing, and the skin surface to be kept the same even for different radii of curvature, i.e. over different parts of the skull. Ultimately it also avoids errors in the initialization measurement, because the dimensions of the initialization element, in particular with respect to the concave or recessed configuration of the underside, correspond to those of the cylindrical body with marking substance or to a receptacle therefor.

In one embodiment the cylindrical housing for the marking device comprises a removable housing lid, preferably made of a transparent plastic, so that the marking substance can be monitored and is also exchangeable.

The marking substance for nuclear-spin tomography is a liquid or a gel that is held in a spherical or closed cylindrical container, such that the outside diameter of the sphere or cylinder corresponds substantially to the inside diameter of the cylindrical housing with catch receptacle or counterpart. The substance to be used is selected such that it is easily visible in the nuclear-spin as well as in the T1 and also the T2-weighted image. The special feature in comparison to known markers is that the latter are ordinarily easily visible only in the T1 or T2 image. At the same time, the marking can be well discerned in computer tomography by way of the difference in contrast between the sphere and the housing. As a result, even if the wrong marking aid is selected, any desired marking chosen by the user can be discerned on the CT or X-ray images with relatively little difficulty. This feature serves to eliminate the need to remeasure the patient in case the wrong marking aid is chosen and, in particular in cases of CT marking, to prevent extra radiation exposure.

It should be noted at this juncture that of course a kinematic reversal of catch knob and receptacle or counterpart is conceivable without departing from the principle in accordance

with the invention, namely the separation of the carrier from the cylindrical container of the actual marking substance.

As described briefly above, in accordance with the invention a initialization element is provided that has a closed shape corresponding in its dimensions and the configuration of its underside to the cylindrical housing. This element comprises on its lid side a marking depression located in a position that is the same as the middle or centre of gravity of the contrast marking substance, i.e. of the spherical or cylindrical container for such a substance. This marking aperture can be contacted with a pointer or stylus to facilitate the initialization measurement.

Preferably the cylindrical housing to contan the marking substance and/or the initialization element consists of a plastic material, and the carrier preferably comprises an adhesive-coated film reinforced on one side in the region of the catch knob.

Specifically for use in the described navigation system a pointer is proposed for the necessary tracking device, such that the pointer has the shape of an elongated handpiece housing within which a preferably encapsulated sensor is present, and at least partially projecting from the housing there is a contact tip or a receptacle for a contact tip or insertion accessory.

In accordance with the invention the encapsulated sensor is rigidly connected to the contact tip or the contact-tip receptacle by means of an element with openings on opposite sides.

The connecting element with sensor and contact tip situated in the respective openings is then mounted so as to be yielding with respect to the handpiece housing, i.e. the mounting is stress-free and quasi-cardanic.

The connecting element is made of a plastic resistant to deformation and thermostable, or of titanium. In order to achieve the desired absence of stress between the connecting element (and hence the composite of sensor and contact tip) and the housing, between the connecting element and the inside of the housing an annular gap is formed. To seal the gap between connecting element and housing, or between an external coupling and the housing, flexible sealing means are provided, preferably flexible sealing rings.

By means of the pointer, i.e. the contact tip disposed there, the operator touches the part of the site that is to be identified and represented by means of the navigation device. The sensor in the handle transmits the position of the pointer, and thus also the position and direction of the tip, to the navigation device. The navigation device then enables the monitor to display a representation based quasi on the position of the tip and the specified orientation in space. For this purpose the positional values are transmitted through a suitable cable connection or by wireless means, so that a virtual representation of the real site is produced.

The pointer thus serves to operate the whole system, wherein a distinction is made, as mentioned at the outset, between an operation field and a control field. When the operator moves the pointer into the control field, it is possible to select and activate menus shown on the monitor, and thus to control the system.

The confirmation or initiation of a selected function can be brought about by a key disposed in the pointer, which is connected by way of a signal lead to the navigation system or the control computer.

The contact tip of the pointer is made of a rigid material, preferably stainless steel or titanium. Alternatively, the above-mentioned tip receptacle can also be used to attach

puncture accessories or accessories for the introduction of catheters and so on. Common to all inserted tips is that they have a point directed towards the object to be investigated, which serves as a reference point for navigation. The reference point itself can be freely chosen. This feature is made possible by the fact that the sensor for the navigation system that is situated in the pointer measures with respect to the specified virtual centre, independently of the system itself. The tip of the pointer is defined by a vector that is calculated with reference to the specified position of the sensor. To determine this vector the initialization procedure mentioned above is needed. In concrete terms, the pointer is moved about its tip at a fixed position, e.g. by means of the initialization element. The navigation system detects this movement with the aid of the tracking device and calculates, on the basis of the known position of the tip, how the tip of the system behaves with reference to the location of the sensor.

The pointer for the tracking device of the navigation system in accordance with the invention is largely liquid- and vapor-tight, so that it can be sterilized by conventional clinical means. The provision of the connecting element and its disposition in the elongated housing ensure that even under mechanical stress and/or during temperature changes the relative positions of sensor and tip remain unchanged, so as to achieve the required precision of position monitoring and navigation.

In the following the invention is explained with reference to exemplary embodiments, the description of which is assisted by figures, wherein

Fig. 1 shows the principles of carrying out an image-assisted navigation procedure;

Fig. 2 shows the arrangement of a transmitter of the tracking device on the operating table;

Fig. 3 shows the arrangement of an additional sensor for detecting the patient's head movement;

Fig. 4 shows the organization of operation field and virtual control field for operating the system by means of pointer or stylus;

Fig. 5 shows a monitor display with the menu for marker recording;

Fig. 6 shows a monitor display with the menu for checking the markers or fiducials;

Fig. 7 shows a monitor display with virtual keypad;

Fig. 8 shows a display including the field for initiating and carrying out intraoperative documentation;

Fig. 9 is a sectional drawing of the separable marking device;

Fig. 10 is a perspective drawing of the complete marking device;

Fig. 11 is a perspective drawing of the carrier for the marking device, but with initialization element attached; and

Fig. 12 is a sectional drawing of the pointer or stylus for the tracking device.

The navigation system according to the exemplary embodiment requires the most accurate possible image data representing the patient's anatomical structures. As shown in Fig. 1, these image data are made available by either computer tomography and/or nuclear-spin tomography.

Computer-tomographic representations are advantageous when bony structures are to be visualized. To represent soft parts such as the brain, nuclear-spin tomography is preferred. For taking the pictures and for subsequent monitoring of position, so-called markers are placed on the patient's head. The markers comprise a liquid or a gel which, depending on the particular tomographic method being used, ensures sufficient contrast in the image that the markers can be identified.

After the data have been transferred by way of a local network or suitable storage media, the scanned images are further processed by an automated system with the aim of obtaining the most authentic possible 3D representation of the brain, to which the surgeon can refer before the operation so as to plan ahead and design a minimally invasive procedure. By means of segmentation steps, mathematical methods are applied to enable particular anatomical structures to be extracted from the complete data sets.

For neuro-navigation it is then necessary to create a registration between the virtual image of the brain, obtained from the scanned data, and the real brain in the operating theatre.

For this purpose unambiguous positions must be established that can be found again in both the real and the virtual system. In order to determine the locations of these sites, additional markers are used to serve as reference points. The markers are situated in the same environment as those that had been used for the MR or CT scanning. Regarding the structure and utilization of the markers according to the exemplary embodiment, see the description of Figs. 9 to 11 below.

For detecting position the navigation system according to the exemplary embodiment comprises a constant-magnetic-field transmitter T, which is connected to the operating table OPT. As shown in Fig. 2, the patient's head can be fixed in place by

a special head holder KH. Within the operation field OF no devices associated with the sensory or navigation system are disposed that might interfere with the surgical operation.

In another exemplary embodiment, illustrated by Fig. 3, an additional sensor is attached to the patient's head; this sensor, called the head sensor KS, is provided so that in case the head is not rigidly fixed, its movements can be detected automatically, eliminating the need for manual calibration following each change in position. The corrective data provided by the head sensor are sent to a control computer (not shown) in order to establish a coordinate system that is quasi-dynamic, or alterable with reference to the source alteration, without impairing the properties of ther navigation system, i.e. the precise registration between virtual image and real appearance.

Because of the fixed spatial relationship between the transmitter T and the patient, mechanical impacts or changes in orientation and movements of the operating table introduce no inaccuracies in the assignment of position and the image displayed on the basis of the stored 3D data sets.

Figure 4 is intended to show how the menus shown in Figs. 5 to 8 can be activated, and control commands initiated, without any input aids apart from the pointer or stylus described below, in that the operation field OF and control field SF are separate from one another and the pointer or stylus is moved inward or outward with respect to these fields.

The relevant switching process involves recognition that a spatial distance or boundary has been crossed. This occurs when the sensor within the pointer, which detects the magnetic field emitted by the transmitter, is situated in or at this boundary region. Appropriate control commands can be triggered or confirmed by an electronic switching element, such as a key, disposed in the pointer housing.

Figure 5 is a hard copy of the navigation screen, i.e. a monitor display, at a time when the procedure is in the stage of recording the markers. As can be seen from the monitor display, up to six (for example) markers are usable, so that a generally high degree of reproducibility is obtained even if a marker becomes detached or must be removed during preparation for surgery. In principle an arbitrarily large number of markers can be used, but an optimal number is 4 or 5.

Figures 6 to 8 show other pictures of the navigation screen to demonstrate so-called fiducial management, the virtual keypad to control the navigation system, and the possibility of intraoperative documentation for subsequent analysis or evaluation of the treatment. With respect to the initialization measurement by means of the initialization elements shown in Fig. 11, it should be noted that this step has the purpose of creating a predetermined spatial (i.e., defined by coordinates) relation of the patient's head to its virtual image displayed on the monitor. To this end, the initialization elements are stuck onto the special carriers that have already been disposed on the patient's skin. These elements, as explained below, comprise depressions that are contacted in arbitrary sequence by the contact tip of the pointer or stylus. That each such position has been reached is confirmed by actuating the above-mentioned key disposed on the pointer. The position itself is recorded by the navigation computer as a result of automatic detection of the location of the sensor disposed in the pointer, and is indicated by the lighting of a switch symbol in the display. After all positions have been recorded, the navigation system is ready for use; in the case of neurosurgical applications, the system is preset in such a way that the 3D image of the brain is first shown from the viewpoint of the surgeon. It is of course possible at any time, by means of the pointer and the function VIEW on the virtual menu, to change this direction of view.

The above-mentioned markers can be removed from the patient's head before surgery is begun, so that they cannot interfere with the procedure.

The marking devices or fiducials for the proposed navigation system will now be explained further with reference to Figs. 9 to 11.

The marking units to be inserted are attached to the relevant object, for instance the human skull, and the contrast substances present in them allow them to be displayed as a group by the imaging procedure currently in use. Independently of this procedure, the position of these marking units can be discerned at a later time, namely in the operating theatre. By comparing and combining the positional data regarding these units that were obtained during the imaging procedure, i.e. are contained in the image data sets, and those that are seen in reality, the coordinates can be matched to one another. This in turn is the basis for the assignment of arbitrary points to places in the coordinate system, so that an appropriate navigation becomes possible.

Figure 9 shows a cross-section through the special, separable marking device. A carrier 600 attached to the subject is preferably made of a piece of plastic film with an adhesive coating on one side. Accordingly, the carrier 600 is constructed as a flat sheet, preferably in a circular shape. The carrier can be variously designed; for instance, it can have a large adhesive surface for adults and a small one for children, and the adhesive in the coatings can be different to suit differentially sensitive skin types. In the exemplary embodiment the catch knob is made of carbon, which offers the advantage that while being mechanically stable, it does not produce an artefact in either nuclear-spin or computer tomography.

On the side of the carrier 600 facing away from the adhesive surface, there is a projecting catch knob 500. This catch knob 500 serves for attachment of a cylindrical housing 200, which on its underside comprises a catch receptacle or counterpart 400. The underside 700 of the cylindrical housing 200 has a concave shape or is recessed correspondingly.

By means of the catch knob 500 and catch receptacle 400 the cylindrical housing can be connected to the carrier 600, which has already been attached to the patent. After the images have been obtained, i.e. after the tomography scanning has been completed, the cylindrical body or housing 200, which is easily handled because it projects outward, is removed from the patient. Then in the operating theatre it can be replaced by the initialization element 900 shown in Fig. 11, in order to carry out the initialization measurement.

As can be seen in Fig. 9, the cylindrical housing 200 comprises an opening that serves to receive a sphere 300, in the interior of which is contained a contrast liquid or gel to be used for nuclear-spin or computer tomography.

The cylindrical housing 200 is closed by a lid 100 that can be removed by a tool and that is preferably made of a transparent plastic material. Because of its transparency, by looking through the lid 100 it is possible to see how much marking liquid remains in the sphere 300. The sphere 300 containing the marking substance can also be exchanged for another suitable container. The fiducials are basically complete structures, which contain spheres that are optimal for the particular imaging technique to be used in each case.

The shape of the underside 700 enables variation in the curvature of objects such as the human skull to be compensated, so that the seating of the marking device does not need to be changed and does not become unstable. Furthermore, this underside 700 can accommodate the above-mentioned recess

serving as catch receptacle 400 or counterpart to the catch knob 500.

The material of which the carrier 600 with its adhesive surface is composed has a flexibility matched to that of the skin and can conform to the surface of the body; nevertheless, it is resistant to distortion of its basic shape, so that the catch knob 500 is always situated in the same place, preferably the middle of the carrier 600, as is required for precise marking. The opening in the cylindrical housing 200 of the marking device is so constructed that the sphere containing the marking substance is held reliably and quasi-immovably in place, i.e. is stably positioned.

Figure 10 shows the complete marking device, i.e. the carrier 600 onto which has been set the cylindrical housing 200 with lid 100.

After the tomography images have been obtained, the cylindrical housing 200 with sphere 300 containing the contrast-marking substance is removed from the carrier 600 by operating the releasable connection, and the patient can then move without hindrance. Because the carrier film remains on the patient, i.e. the carrier 600 with catch knob 500 is still adhering, it is possible to carry out the desired initializing measurement preoperatively with exact assignment of positions. For this process the accessory shown in Fig. 11, in the form of an initialization element 900, is set onto the carrier. The initialization element preferably consists of a solid plastic body, the crucial feature of which is a depression 800 it its centre that corresponds in position precisely to the midpoint or centre of gravity of the sphere 300 that contains the marking substance. This ensures that during initialization with the pointer or stylus, the virtual and the real spherical centre of the marking device coincide. Hence after the initialization measurement, it is possible to superimpose precisely the virtual images from the navigation system and the

real skull. After initialization has been completed, the initialization element or the entire marker, i.e. including the carrier, can be removed from the head.

Regarding the design of the pointer or stylus for a tracking device associated with the navigation system presented here, reference is made to the sectional drawing shown in Fig. 12.

The pointer comprises a contact tip 1, or else a contact-tip receptacle that can also be used to hold various accessories. Opposite thereto is a special electromagnetic sensor 5. The sensor 5 and the contact tip 1 are fixedly connected to one another by an element 3. The element 3 in turn is mounted quasi-cardanically, i.e. is yielding and stress-free with respect to the actual handle, the elongated handpiece housing 8.

The connecting element 3 is preferably made of a plastic material that resists deformation and is thermostable, or of titanium.

In the elongated housing 8 is an opening within which is seated a key 6. The electrical output wires from the sensor 5 and from the key 6 are combined within a signal lead 7 that runs out of the handpiece.

The key 6 is fixed within the handpiece housing 8 in a vapour- and liquid-tight manner.

At the end of the housing 8 opposite the contact tip 1, i.e. opposite the distal end of the pointer, is situated a vapour- and liquid-tight cable outlet 9. Both the connecting element 3 and the cable outlet 9 are attached to the housing 8 in a mechanically releasable manner, by the external couplings 2, 10. To ensure a sufficiently tight seal, flexible sealing elements are provided in the region of the couplings 2 and 10, preferably in the form of sealing rings 4 and 11.

The connecting element 3 is so disposed that at least its sensor-receiving opening, and hence the sensor 5, is within the housing 8, an annular gap 12 being formed between the connecting element 3 and the inside of the housing.

By means of the contact tip 1 the object to be navigated is touched, in which process the relevant position is determined by association of sensor 5 and contact tip 1 and the resultant vector. The location and orientation thus determined are used by the control computer of the navigation system to select those virtual images that can be seen in the direction of view, so to speak, of the contact tip.

The connecting element 3 preferably is made of a deformation-resistant and thermostable plastic or titanium. By using such a material, the desired firm connection between contact tip 1 and sensor 3 is ensured, while simultaneously the mechanical contact with the housing 8 is reduced to a minimum by the annular gap 12. Deforming forces that act, for example during steam sterilization, on the pointer and in particular on its housing are kept away from the composite arrangement comprising tip 1, element 3 and sensor 5.

The embodiment of the stylus shown here presupposes an exchange of signals with the navigation device by way of wires. Alternatively, however, wireless communication by way of telemetry apparatus known per se can be employed.

As the sensor 5 a known magnetic-field sensor is preferably used. Such a sensor can detect sensor position in six degrees of freedom, and the range of sensor movement is not restricted. The magnetic-field sensor detects its position, or the position of the contact tip 1 with respect to its own position, on the basis of a DC magnetic field present in the navigation environment, by appropriate real-time measurements of field strength.

The special sensor is capable, in combination with an associated evaluation device and the above-mentioned transmitters, of carrying out up to 144 measurements per second with an angular resolution of ca. 0.1°. The output data are available in a cartesian coordinate system with orientation angles, as well as in the form of a rotation matrix.

Altogether, the present invention discloses a navigation system that succeeds in generating virtual representations of, for example, the brain of a patient that corresponds with high precision to the real picture, by combining a special tracking sensor system and a 3D-image processing based on CT and MR data. As a result, the particular strategy for a therapeutic operation can be optimized both pre- and interoperatively. Because there is no need for supplementary units to manage the system or for an elaborate control mechanism, such a navagation system can be employed with minimal personal effort and material expenditure.

List of reference symbols

OF	Operation field
SF	Control field
KH	Head holder
T	Transmitter
OPT	Operating table
KS	Head sensor
1	Contact tip
2, 10	External coupling
3	Connecting element
4, 11	Sealing rings
5	Sensor
6	Key
7	Signal lead
8	Housing
9	Cable outlet
12	Annular gap
100	Lid
200	Cylindrical housing
300	Sphere with marking substance
400	Catch receptacle
500	Catch knob
600	Carrier
700	Underside
800	Marking recess
900	Initialization element